# Protection of Participants in Behavioral and Social Sciences Research

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Are you conducting research with human subjects?

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Researchers conducting behavioral and social sciences research often have questions about the applicability of their research to the Federal regulations protecting human subjects (research participants). Basic questions arise including even "Am I conducting research that involves human subjects?"

This document addresses many issues including:

- The definition of human subjects.
- What you need to do to comply with Federal requirements if your research involves human subjects.
- The role of your Institutional Review Board (IRB) and the types of review it conducts.
- How to decide if your research falls into an exemption category and does not require IRB approval.
- Informed consent requirements.
- Privacy and confidentiality including applying for a certificate of confidentiality.
- Key points when applying for federal funding.
- Additional resources.

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This document is also available as an Adobe Acrobat file.


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# Are You Conducting Research With Human Subjects?

Human subjects are living individuals about whom an investigator conducting research obtains (1) data through intervention or interaction with the individuals, or (2) identifiable private information. Regulatory requirements to protect human subjects (research participants) apply to a much broader range of research than many investigators realize, and researchers obtaining new data or using existing data are often unsure about how regulations apply to their research. Regulatory and ethical obligations to protect research participants apply, for example, to research that uses:

- **Data from varied research methods** including surveys, interviews, and observation;
- **Private information,** such as medical, family, or employment information, or residual administrative records including earnings, and treatment histories that can be readily identified with individuals, even if the information was not specifically collected for the study in question;
- **Tissue specimens,** obtained for routine medical care that would have been discarded if not used for research, or **DNA samples**, where samples or specimens can be linked to a living individual. (For detailed information, see Research on Human Specimens (Brochure) www.cdp.ims.nci.nih.gov/policy.html

**If so, you must...**
comply with your institution's rules and the requirements of your Institutional Review Board (IRB) as well as meet the Federal requirements[1] in order to carry out your research. Some institutions have requirements that exceed those of the State and Federal regulations. If you have any doubts about whether you need IRB approval, ask your IRB chair for clarification[2]. If you apply for an NIH grant, or respond to a Request for Proposal (RFP), failure to follow your institution's procedures, or to document the use of human data in your grant application or contract proposal, may delay or prohibit funding.

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1. Title 45 Code of Federal Regulations (CFR), Part 46, Protection of Human Subjects (June 18,1991).
2. If your institution has no IRB, you may establish an IRB at your own institution or you may obtain approval for your plan to involve human subjects from an IRB elsewhere that satisfies all Federal requirements. For information about these options, contact the Office for Human Research Protections.

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# What Is The Role of Your Institutional Review Board?

Your IRB must review and approve research protocols, including surveys and other data collecting instruments, if human subjects are involved, or it must verify that the research meets criteria for exemption. This process is designed to protect the rights and welfare of human participants by selecting them equitably, obtaining informed consent, minimizing risks, and ensuring privacy and confidentiality.

**No NIH grant or contract funds can be expended for research involving human participants and individuals cannot be enrolled, until IRB approval is obtained, unless the research is exempt.** The IRB must review and approve the project at least once a year and whenever changes occur in the protocol or procedures.

**The IRB must be notified of any unanticipated problems** involving risks to subjects or others, including physical or psychological injury to subjects, improper disclosure of private information, economic loss, or other potentially harmful occurrences.

## Types of IRB Review

**Full Board Review**
Review of proposed research at a convened meeting at which a valid quorum of IRB members is present. For the research to be approved, it must receive the approval of a majority of those members present.

**Expedited Review**
Review of proposed research by the IRB chair or a designated voting member or group of voting members rather than by the entire IRB. Federal rules permit expedited review for certain kinds of research involving no more than minimal risk and for minor changes in approved research.

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# What Consent is Required when Obtaining Data from Research Participants?

IRBs are responsible for ensuring that informed consent will be sought and documented from each participant in accordance with federal regulations. The IRB may waive the requirement for informed consent if the risk to the participant is minimal and if certain other conditions are met.[1]

**You should not assume that your research poses minimal risk just because it involves only interview or survey data collection.** Sensitive questions may be included leading to distress that exposes subjects to greater than minimal risk. Loss of confidentiality can cause harm to subjects, their relatives, and to others. IRBs consider the risks and whether privacy and confidentiality protections described in your research project are adequate.

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[1]Title 45 Code of Federal Regulations, Part 46 116(d)

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# Is Your Research Exempt From IRB Review?

Research using data from living persons does not require IRB approval when the research either does not involve human subjects as defined in the Code of Federal Regulations (45CFR46) Protection of Human Subjects (Subpart A is the Common Rule), or the only involvement of human subjects is in one of the 6 "exempt" categories listed in the Code. Exemptions most pertinent to work with human data are Exemptions #1, #2, and # 4.

**As stated in 45 CFR 46.101(b):**
(1) Research conducted in established or commonly accepted educational settings, involving normal educational practices.

(2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, **unless:**

> (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; **and**
>
> (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

(4) Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

Sensitive information reasonable persons would not want disclosed is exempt only when the research participants cannot be identified directly or through identifiers linked to them.

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**What is meant by "existing" data?**
The term "existing data" applies to retrospective studies involving already collected data where data must be "on the shelf" when the protocol is initiated. For research supported on NIH grants or contracts, the data should be in place when the application or proposal is submitted for IRB review.

Some researchers mistakenly believe that **secondary data** analyses using existing data to address new research questions are always exempt. Exemption #4 does not apply to existing data as long as participants can be identified. A status of **"No Human Subjects"** applies when data are given to a researcher by others after being **permanently and completely delinked** from the identity of living subjects. Check with your IRB to see if approval is necessary, especially if any data may be linked to research participants.

**What is meant by "identifiers linked to the subjects"?**
Identifiers such as names, Social Security numbers, medical record numbers, and code numbers permit data to be linked to individual people and perhaps also to associated medical, financial, or employment information. Exemption # 4 applies most clearly to **behavioral and social sciences research** (BSSR) data where such personal identifiers do not accompany the data provided to or utilized by the researcher. Your IRB will determine whether Exemption #4 applies when you receive coded BSSR data from a collaborator or other source.

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**What is meant by "publicly available sources"?**
This refers to public sources of data, such as telephone books and public records. Although there are organizations that make data sets broadly accessible at reasonable cost to the research community, these materials are not usually available to the public at large. If you obtain data from any of these sources, you should not assume that the source meets the definition of "publicly available." It is up to your IRB to decide.

**What about behavioral and social sciences research (BSSR) data obtained from a data bank or archive?**
BSSR data obtained from a data bank or archive may be exempt depending on the policies and procedures to prevent the release of personal identifiers. There are many kinds of data banks that operate in different ways. Your IRB will need

to determine whether the questions you will ask and the bank you will use meet the requirements for an Exemption.

**How can you determine if your research is exempt?**
Human subjects regulations decision charts from the Office for Human Research Protections (OHRP) are available from their website at:

http://ohrp.osophs.dhhs.gov/humansubjects/guidance/decisioncharts.htm

This information will suggest whether your research falls under the human subjects regulations and if so, whether it is likely to require IRB review, is exempt from IRB review, or is a candidate for a waiver or alteration of informed consent. You should be aware, however, that institutions vary in their requirements for IRB review and usually have an official authorized to determine exempt status. **You must check with YOUR institutional officials to determine whether full, expedited, or no IRB review is required for your proposed project.**

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# If You Obtain Data from Other Researchers, Is IRB Approval Required?

**YES!**
Unless your research is exempt, BOTH you and the other researchers must have approvals from the IRBs at your respective institutions.

**What if these researchers are located outside the U.S.?**
They will need to contact the funding authority to request that OHRP solicit any required assurances to comply with acceptable procedures to protect human participants and to provide documentation that their IRB meets the requirements defined in U.S. laws. Engaged sites will normally need to obtain approval from their local IRB. An assurance coordinator at OHRP can assist you with this process once contacted by the funding authority. Finally, your NIH program official usually needs to request State Department clearance for your project.
http://ohrp.osophs.dhhs.gov/humansubjects/assurance /engage.htm

Obtaining approvals and assurances takes time, particularly if institutions are located overseas. No NIH funds can be expended for studies involving research participants and individuals cannot be enrolled until the necessary approvals and assurances are in place. **Start the process early!**

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# What Key Points Should You Address in Your Research Application / Proposal to the NIH?

The Public Health Service (PHS) grant application kit (PHS Form 398) requires information about the involvement of research participants in the proposed research, the research risks, and the protection against these risks. The face page of the application asks you to certify whether human subjects are involved and if Yes, whether you claim an exemption. Additional information must be provided in the Human Subjects section (e.) of the Research Plan. It is important to state whether the data already exist or will be collected prospectively and whether subjects can be identified directly or through identifiers linked to the subject. Address recruitment, consent, potential risks and safeguards, risk-benefit ratio, privacy and confidentiality. This information should be provided for all data, including those obtained from other researchers.

**Note, privacy and confidentiality are particularly important for persons who are research participants whenever data are sensitive and identifiers exist.** If you have claimed an exemption on the face page, you should provide sufficient information in the Human Subjects section and in the body of the application to show that the exemption is appropriate.

When preparing contract proposals in response to a Request for Proposals (RFP), the Instructions to Offerors (Section L) of the RFP specifies the required policies and requirements when human participants are involved in the project; the same information as indicated earlier for grant applications must be provided in your proposal.

The NIH Scientific (peer) Review Group (SRG) will review the information you provide in the grant application or proposal. The SRG will determine whether plans and approvals for involving human subjects are appropriate, including the involvement of women, minorities, and children. Any concerns about protection of human subjects are noted by the SRG and are transmitted to the NIH awarding unit or the contracting officer. The NIH awarding unit staff/contracting officer, in consultation with the NIH Office

of Extramural Research (OER), is responsible for ensuring that any human participants concerns are resolved prior to funding or enrollment of human subjects. NIH staff members are responsible for ensuring on an annual basis that there are no major changes in the human subjects research and that annual IRB approvals are obtained.

If an award is being made by the NIH and your institution does not have an applicable Assurance, the funding authority must contact OER. OER will consult with OHRP as needed. Before an award can be made, you must supply the applicable Assurance number, the IRB approval date, and whether the approval was by full IRB review or by expedited review.

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**Should you apply for a Certificate of Confidentiality?** If your research involves collection of information that can be considered sensitive because it: could be damaging to an individual's financial standing, employability, insurability, or reputation; or could lead to social stigmatization or discrimination; or your study involves genetic testing for disease predisposition, or information about sexual attitudes or practices, substance abuse or other illicit behavior, you may want to request a *Certificate of Confidentiality* from the NIH. These certificates protect the investigators and others with access to research records from having to disclose identifying information in any civil, criminal, legislative, administrative, or other Federal, State, or local proceedings unless the subject consents. Certificates are issued sparingly, only when research information is sensitive and protection is necessary to achieve the research objectives while protecting confidentiality and privacy. Apply to the NIH after you receive your award, and have IRB approval, but before you begin your study. Federal funding is not a prerequisite.

**From time to time changes are made in human subjects regulations and in their interpretation by IRBs and by OHRP. It is important to review and understand the current regulations before submitting your grant application and particularly before starting research. Always check with your local IRB for guidance.**

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# Where Can You Find HELP and Get Additional Information?

- Your local Institutional Review Board (IRB)
- Your NIH Institute/Center Program Official
- The following web sites:

The Office for Human Research Protections (OHRP)
http://ohrp.osophs.dhhs.gov

Bioethics Resources on the Web
http://www.nih.gov/sigs/bioethics

National Institutes of Health (NIH)
http://www.nih.gov

NHGRI Ethical, Legal, and Social Issues Program
http://www.nhgri.nih.gov/ELSI

National Bioethics Advisory Commission (NBAC)
http://bioethics.gov/

45 CFR 46, Subparts A-D, Protection of Human Subjects,
(The Common Rule is Subpart A)
http://ohrp.osophs.dhhs.gov/humansubjects/guidance/ 45cfr46.htı

Research on Human Specimens (Brochure)
http://www.cdp.ims.nci.nih.gov/policy.html

This brochure is available electronically at:
http://obssr.od.nih.gov/IRB/protect.htm
The website will reflect current information.

Portions of this brochure were adapted from the brochure: *Protecting Human Research Subjects within the U.S. Department of Energy* by Susan L. Rose, PhD, http://www.er.doe.gov/production/ober/humsubj/brochure /brindex.html & the *Research on Human Specimens* Brochure cited above.